

Docket No.: 05986/100K504-US1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Marco PAPPAGALLO

Application No.: 10/624,942

Confirmation No.: 7691

Filed: July 21, 2003

Art Unit: 1617

For: TREATMENT OF SPINAL MECHANICAL
PAIN

Examiner: Jennifer M. KIM

DECLARATION OF DR. MARCO PAPPAGALLO UNDER 37 C.F.R. 1.132

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Marco Pappagallo, declare that:

1. I am a U.S. citizen and am more than twenty-one years of age.
2. I am the inventor of the above-referenced application.
3. I presently hold the position of Director of Pain Medicine Research and Development at Mount Sinai School of Medicine in New York, New York. I am also a Professor of Anesthesiology in the Department of Anesthesiology and Pain Medicine at the Mount Sinai School of Medicine.
4. I received my medical degree from the University of Rome in 1982, and completed my residency in neurology at the State University of New York at Stony Brook in 1990. I was a clinical and research fellow in pain medicine at The Johns Hopkins Pain Treatment Center in Baltimore Maryland from 1990 to 1993.

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5. I have been an attending physician since 1993.

6. From 2003 to the present, I have been an attending physician in the Department of Pain Medicine & Palliative Care at Beth Israel Medical Center in New York, New York.

7. From 2006 to the present, I have been an associate attending physician in the Department of Anesthesiology at Mount Sinai Hospital in New York, New York.

8. A copy of my curriculum vitae is attached as Exhibit A.

9. I have read and am familiar with the above-referenced application and its file history, including the Office Action mailed March 5, 2007.

10. I have read and am familiar with Geusens et al., "Recovery from Severe Glucocorticoid-Induced Osteoporosis in an Adolescent Boy," Journal of Clinical Densitometry, 2001;4(4):389-394 ("Geusens").

11. Geusens reports the case history of an adolescent male with moderate to severe osteoporosis (see, e.g., the patient's bone mineral density scan Z-score of -5.5 in the spine; Geusens, page 390, left column, 2nd paragraph).

12. Figure 1 on page 391 of Geusens includes three imaging studies of the patient's spine, an MRI in panel (A) and plain X-rays in panels (B) and (C).

13. Based on the X-rays shown in panels (B) and (C) in Figure 1 of Geusens, and the patient's medical history, the patient has osteoporotic vertebral compression fractures.

14. The diagnosis of osteoporotic vertebral compression fractures in the patient reported by Geusens is based on the following criteria: the height of the vertebral bodies is decreased as shown in the X-rays in panels (B) and (C) of Figure 1, the fractures involve the body of the vertebrae only, the patient has underlying osteoporosis, and the patient does not have a history of trauma that would account for the fractures.

15. I declare further that statements made in this declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made

are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated: 6/5/07

Marco Pappagallo, M.D.